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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,072	11/04/2004	Andrea Trombi	024931-00026	2437
4372	7590	06/12/2007		
ARENT FOX PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER ALI, SHUMAYA B	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/512,072	Applicant(s) TROMBI, ANDREA	
	Examiner Shumaya B. Ali	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

Applicant's argument with respect to "claimed valve is able to oppose a minimum resistance to opening and closing during the inspiration and expiration stage of use by an operator" (see argument filed on 3/14/07, page 5, lines 8-10) is fully considered but they are not persuasive because argument which Applicant relies upon are not supported in the claims.

Applicant's argument with respect to "the shutter 63, ring 52 and spring 84 [of Blacker] are not integrally provided in and define a body of the valve 60. Rather, the shutter 62, ring 52 and spring 84 are separate and distinct component that must first be manufactured separately and then assemble to define the valve 60" (see argument filed on 3/14/07, page 5, lines 18-21) is not well taken. First, the manufacturing component is not supported by the claims. Second, Blacker teaches, "the component parts [valve assembly 60] of housing 12 may be formed of separate, multiple pieces of material that are connected together by welding, adhesive, etc., or more preferably, some of the component parts may be formed together with a single piece of material formed by an injection molding process" (see col. 2, lines 65-67 and col.3, lines 1-4). Thus, Blacker teaches the valve components, shutter, ring, and spring can be integrally formed to define a single body.

Applicant further argued that Blacker lacks the valve is made of a "polymeric material" (see remark filed on 3/14/07, page 4, lines 20 and 21). This argument however is not well taken because Blacker teaches, "any of a number of types of plastic may be used to construct ... parts

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of the nebulizer” (see col. 3, lines 5-7), which reads on claimed “polymeric material”. Thus, Blacker teaches “polymeric material.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Blacker et al. US Patent No. 6,450,163 B1.

As to claim 1, Blacker in a breath actuated nebulizer see figures 1-3 discloses an apparatus for nebulizing a liquid, in particular for aerosol therapy, the apparatus comprising: a nebulizing ampoule (14) provided with at least one opening (70) for aspirating and/or expelling air from/to the environment and with a mouthpiece (98) for dispensing a nebulisation of medical product; and a valve (60) for regulating a flow of air into an/or out of the ampoule said valve being positioned in correspondence with said at least one opening and comprising a shutter (62) able to move between an operative blocking configuration corresponding to an obstruction of said at least one opening and an operative configuration of consent to the passage of the flow of air (col.5, lines 15-20), a ring (52) connected to the shutter to anchor the shutter to a tubular

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portion of the ampoule said tubular portion being positioned in correspondence with the at least one opening and a plurality of deformable connecting elements (84) between the ring and the shutter to allow said shutter to move from said operative blocking configuration to said operative configuration of consent and vice versa, said movement being directly caused by an inspiration and/or expiration phase by a user, the deformable elements are spiral shaped and have a first end fastened peripherally to the shutter and a second end fastened to the ring (co.4 lines 39-67, col.5 lines 1-40) . Blacker further discloses wherein the shutter, the ring and the deformable elements are integrally provided in and define a single body of the valve (see col.2, lines 65-67 and col.3, lines 1-4) and wherein the single body is made of a polymeric material (see col.3, lines 4-9).

As to claim 3, Blacker discloses a holed protective element (56) positioned in correspondence with the at least one opening to prevent the introduction of foreign bodies into the ampoule.

As to claim 4, Blacker discloses a second shutter (100) to cover a first opening of the ampoule necessary to expel to the environment air exhaled by a user, said second shutter being a deformable body having an end fastened in correspondence with the first opening and an end that is free to move away from the first opening to uncover the first opening at least partially and allow the escape of air (see fig. 3, col.6 lines 61-64)

As to claim 5, Blacker discloses wherein the valve is associated with a supplementary channel (20) of the ampoule.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blacker et al. US Patent No. 6,450,163 B1.

As to claim 6, Blacker lacks the explicit teachings of wherein the polymeric material is rubber. However, Backer teaches that the components of the nebulizer can be made from “any of a number of types of plastic” (see col.3, lines 6-9). Claimed “rubber” is considered within the range of “a number of types of plastic” taught by Blacker. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the valve assembly with rubber because it is known in the art that valve assembly can be constructed from a number of types of plastic as taught by Blacker.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

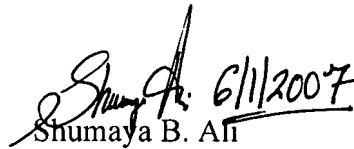
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-8:30pm and Tu-Th 8:00am-1:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Shumaya B. Ali

Examiner
Art Unit 3771



JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
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6/8/07